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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,863	01/15/2004	Leonard Presta	P1726R1D1	5958

9157 7590 01/22/2007

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/757,863	PRESTA, LEONARD	
	Examiner	Art Unit	
	Chun Crowder	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 December 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *09/22/2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *19 and 20*.
   Claim(s) withdrawn from consideration: _____.

PHILIP CAMBEL, PH.D JD
PRIMARY EXAMINER
TC 1600
1/13/07

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Continuation of 11. does NOT place the application in condition for allowance because: for reasons of record, applicant's arguments and the examiner's rebuttal are essentially the same of rcord. Applicant argues that Idusogie et al. (US Patent 6,528,624) is not a prior art under 35 U.S.C. 102(e) because it teaches that substitution at position 334 "had little or no effect on C1q binding or complement activation". This is not found convincing for reasons of record. Furhter, the instant pending claim 19 does not recite specific positions of the Fc region and the functional limitation being claimed is "antibody-dependent cell-midiated bytotoxicity (ADCC)" not c1q binding or complement activation. Given that Idusogie et al. teach method of making and using a variant of a parent antibody which binds CD20 comprising amino acid substitutions in the Fc region (e.g. position 334, see column 4 and 40 in particular), the prior art antibody variant would inherently have the claimed functional limitation of "mediate antibody-dependent cell-midiated bytotoxicity (ADCC) in the presence of human effector cells more effectivley".

Therefore, the reference teachings anticipate the claimed invention.

Applicant's arguments and the examiner's rebuttal regarding the rejection under 35 U.S.C. 112, first paragraph are essentially the same of record. Applicant further argues that anti-CD20 antibodies have been shown to be therapeutically effective for both lymphoma and leukemia and anti-CD20 antibody variants with improved ADCC function have been indicated effective in mammals. This is not found persuasive for reasons of record. Further, independent claim 19 recites "at leat one amino acid modification" without setting forth specific amino acid residues and specific positions in the Fc region; as such, it is not clear what position in the Fc region of the anti-CD20 antibody can be modified to achived the claimed function of "mediates antibody-dependent cell-medialted cytotoxicity in the presence of human effector cells more effecdtively" the antibody would maitain its activity. Even in the cases that the host effector mechanisms to monoclonal antibody activity are evaluated in vivo, the results often cannot simply be used to predict clinical efficacy because monoclonal antibodies behave differently in different experimental systems, thus even the data from in vivo animal experiments do not translate to therapeutic effect in heterogeneous human cancer patients (Eccles, Breast Cancer Res. 2001, 3:86-90, see entire document, particularly pages 87-88, and Tutt et al. The Journal of Immunology, 1998, 161:3176-3185. See entire document, particularly pages 3180-3184).

Therefore, the The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.